FEB 17 2006

K053558

Exhibit IV: 510(k) Summary

Schick Ceph Model 4900

Common/Classification Name: "DIGITAL X-RAY EXTRAORAL SOURCE SYSTEM"
21CFR872.1800

Schick Technologies, Inc.
30-00 47th Avenue
Long Island City, NY 11101
718-937-5765, 718-937-5962 (FAX)
Contact: Daniel Michaeli, Prepared: December 1, 2005

A. Legally Marketed Predicate Devices

KODAK T-MAT G FILM SO-381 (K837506) is a legally marketed predicate receptor that is indicated for cephalometric examinations. The CDR PANX, MODEL 4792 (K031291) is a legally marketed predicate x-ray generator indicated for extra-oral dental exams, and will be utilized as the host generator on the Ceph Model 4900. The integrated software is similar to that utilized in the COMPUTED ORAL RADIOLOGY SYSTEM (K041385).

B. Device Description

The Ceph Model 4900 is intended to replace x-ray film in the acquisition of diagnostic cephalometric x-ray images of the skull as are commonly used in orthodontics to measure skeletal changes and monitor oral growth and development. The device works with a cleared x-ray device, along with a specialized collimator and positioning elements that are bundled together and sold as the PanCeph system.

C. Indications for Use

Ceph Model 4900 is indicated for individuals who require extra-oral dental – radiographic examinations.

D. Substantial Equivalence Summary

The Ceph Model 4900 has the similar indications for use and is substantially equivalent to other cephalometric units currently marketed in the U.S (e.g. K837506). The already cleared CDR PANX, MODEL 4792 will be utilized as the

extra-oral generator for this device. The device utilizes substantially equivalent software to the COMPUTED ORAL RADIOLOGY SYSTEM.

E. Testing

The device has been tested to comply with applicable electrical safety standards required for CE marking. It also complies with FDA documents "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" and "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". A radiation survey has confirmed that the system, when used with the generator, imparts similar scatter, and less dose as compared to the film predicate.

F. Conclusions

Schick Technologies has demonstrated through careful analysis and validation studies that the device is substantially equivalent to the already cleared and marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2006

Schick Technologies, Inc.
% Mr. Daniel W. Lehtonen
Staff Engineer-Medical Devices
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K053558
Trade/Device Name: Ceph Model 4900
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: February 2, 2006
Received: February 3, 2006

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053558

Device Name: Ceph Model 4900

Indications For Use:
The Ceph Model 4900 is indicated for individuals requiring extra-oral dental examinations.

Prescription Use _____x_ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David B. Kopman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053558